AQUANOR
MARKETING INC.

April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Resources
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA Docket No. 02N-0278, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness & Response Act of 2002

Dear Sir of Madam:

Aquanor Marketing, Inc. appreciates the opportunity to offer written comments on the Food and Drug Administration's (FDA) notice of proposed rulemaking, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Federal Register 5428.

Aquanor Marketing commends the agency for proposing expeditiously the implementing regulation for this section of Bioterrorism Act in the interest of providing adequate time to comment prior to reaching a final rule. We wish to assist in the goal of assuring that the U.S. food supply remains safe. However, there are substantial concerns regarding the system proposed by FDA to implement the prior notice provisions of the Bioterrorism Act. Aquanor Marketing is a member of the National Fisheries Institute (NFI) and agrees with NFI's position that the complexity of and lack of flexibility in the proposed system renders it unworkable. NFI is submitting comments to this docket and Aquanor Marketing wishes to support and incorporate those comments herein by reference.

We are also in substantial agreement with the following observations and recommendations made in NFI's comment letter:

Observations

- FDA has made little effort to customize the prior notice rule to allow for differences in the nature of imported food or the manner of transportation.

02N-0278 C163

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- FDA has substantially increased the amount of information necessary for prior notice submission beyond the seven basic elements named in the Bioterrorism Act without adequately explaining the rationale for this enormous expansion and full consideration of the importer's ability to obtain this information in the specified time frame.

- After electing to vastly expand the amount of information necessary for prior notice, FDA concludes that it must develop a stand alone system separate from the Customs Automated Commercial System (ACS). However, it does not acknowledge that the incompatibility is largely due to its own expansion of the data elements required for prior notice.

- FDA indicates in its analysis that all or most of the information that it proposes to include in the prior notice system is available at the time of ordering the product. Very often, particularly in the fresh fish business, this is simply not true. Many contracts with shippers call for a variety of species to be delivered depending on availability of the harvest. Species and amount of fish in an entry and much of the arrival information are not known by noon the day before arrival.

- FDA established a minimum time frame for prior notice submission (i.e. noon the day before the shipment arrives) that in many cases cannot be met by significant segments of the food industry, including fresh fish and shellfish.

- FDA's effort to provide a small amount of flexibility, through amendments and updates is far too limited to substantially reduce the likelihood of unacceptable prior notice submissions due to changing or unavailable information.

- FDA has grossly underestimated the training costs and other implementation costs for the proposed rule.

Recommendations

1. FDA should reduce the amount of information that must be included in the prior notice so as to be consistent with the Bioterrorism Act or, at minimum, adopt a prior notice requirement that does not mandate (except for grower identification, if known) more information than the U.S. Customs Service (Customs) requires;

2. Consistent with the recommendation above, adjust the information required in the prior notice then re-consider coordinating with Customs to use the ACS to avoid duplication of effort;

3. Adopt a four hour prior notice requirement with ability to amend up to the time of entry and, where necessary, such as with air and truck shipments of perishables, up to three hours after arrival at the port of entry;

4. Allow amendments to correct inadvertent filing errors;

5. Do not invalidate prior notice submissions that are flagged for an amendment and subsequently go without amendment;

6. Tailor prior notice requirements to accommodate different modes of transportation (rail, vessel, air, truck) and different food products (perishable, non-perishable, short and limited shelf life, temperature sensitive, etc.). Allow air and truck shipments more than one amendment up to three hours after arrival;

7. Follow, obtain from, and coordinate with Customs on day, time, and port of entry information;

8. Limit grower identity information to known growers of raw agricultural products;

9. Clarify and limit "article of food" definition;

10. Provide for verification or validation of prior notice entries; and

11. Allow for back-up system practice.

These points are elaborated further in NFI's comments, thus we appreciate your further attention to its letter. In addition, we would like to add the following comments… [if any add them].

Thank you for opportunity to comment on the proposed prior notice regulation.

Sincerely,

Eric Kaiser
Vice President

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Dear Sir of Madam:

Enclosed is a copy of our comment letter that was filed online.

Sincerely,

Eric Kaiser
Vice President

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